

PATENT
574313-2250.1**REMARKS**

Reconsideration and withdrawal of the claim rejections are requested in view of the remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 12-22 are pending in this application; claims 12-15 and 19-22 are amended. Support for the amendments can be found throughout the specification. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. Amendments to the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§§101, 102, 103 or 112. Rather, these changes are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE DOUBLE-PATENTING REJECTION IS ADDRESSED

Claims 12-15 and 18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 84-91, 93-95, 141-143, 149 and 150 of U.S.S.N. 09/760,574. As has been pointed out previously, the issue of whether there is double patenting is contingent upon whether the claims of the pending applications are allowed, and in what form. For example, claims 141-143, 149 and 150 of U.S.S.N. 09/760,574 have been withdrawn from consideration, and may be cancelled and pursued in a separate application. Applicants believe that this application is in condition for allowance. Accordingly, it is requested that the provisional double-patenting rejection be withdrawn in this application and issued in U.S.S.N. 09/760,574, as is proscribed by MPEP §804(I)B.

III. THE REJECTION UNDER 35 U.S.C. §103 IS OVERCOME

Claims 12-15 and 18 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Klippmark *et al.* in view of Suzu *et al.* and in further view of Felgner *et al.* and Crowe *et al.* These references were also considered in light of the teachings of Wathen *et al.* and Babiuk *et al.* The rejection is traversed.

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The instant invention relates to an immunogenic composition or vaccine against BPIV-3 consisting essentially of one or more DNA plasmids that express BPIV-3 HN protein, F protein or both HN and F proteins. As was demonstrated by the data presented in the Declaration by Dr. Jean-Christophe Audonnet under 37 C.F.R. §1.132, filed on November 3, 2003, the claimed compositions are efficacious as vaccines in bovine animals. The fact that the plasmid DNA compositions of the invention can act as vaccines and confer protection is surprising and unexpected.

The teachings of the prior art have been discussed thoroughly in previous submissions. The cited references do not teach or suggest, alone or in any combination, the currently claimed invention, particularly since Morein teaches the necessity of an adjuvant in larger animals.

The composition and vaccine claims of the instant application recite the transition “consisting essentially of”, which “excludes ingredients that would materially affect the basic and novel characteristics of the claimed composition.” *Atlas Powder Company v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984). “By using the term ‘consisting essentially of’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). “[A]n ingredient has a material effect...if the effect is of importance or of consequence to those of ordinary skill in the art.” *Id.*

As has been discussed and demonstrated experimentally in the current case, the inventors are the first to show a protective effect in bovines against bovine parainfluenza virus type 3 (PI-3) using a DNA plasmid vaccine. The immune response was elicited in the absence of immunostimulants or other adjuvants, which would be considered by one of ordinary skill in the art to have a material effect on the composition. Thus, such ingredients would be excluded by the recited transition “consisting essentially of”.

It should be noted that the claimed compositions and vaccines can include “one or more plasmids” encoding PI-3 HN and/or F proteins. Support for this embodiment can be found throughout the specification, particularly on page 5, lines 11-14. The Declaration by Dr. Jean-Christophe Audonnet that was filed on November 3, 2003 describes experiments in which the HN and F genes were administered on separate plasmids.

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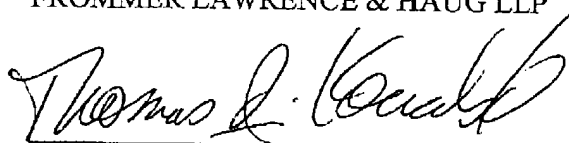
It is submitted that the claimed invention is not obvious over the cited references. Therefore, reconsideration and withdrawal of the 35 U.S.C. §103 rejection are respectfully requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Alternatively, consideration and entry of this paper are requested, as it places this application into better condition for purposes of appeal.

Respectfully submitted,
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